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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,657	09/05/2006	Ashok Kumar	124907-00106	1717
27557	7590	12/17/2008	EXAMINER	
BLANK ROME LLP			MORRIS, PATRICIA L	
600 NEW HAMPSHIRE AVENUE, N.W.			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20037			1625	
			MAIL DATE	DELIVERY MODE
			12/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,657	KUMAR ET AL.	
	Examiner	Art Unit	
	Patricia L. Morris	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 October 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 32-75 is/are pending in the application.

4a) Of the above claim(s) 32-55 and 68-75 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 56 is/are rejected.

7) Claim(s) 57-67 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date. _____ .

3) Information Disclosure Statement(s) (PTO/SB/08)

5) Notice of Informal Patent Application

Paper No(s)/Mail Date. _____ .

6) Other: _____ .

DETAILED ACTION

Claims 56-67 are under consideration in this application.

Claims 32-55 and 68-75 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

The requirement is still deemed sound and proper and is therefore made FINAL. It is suggested that the non-elected claims be deleted.

This application contains claims 32-55 and 68-75 drawn to an invention nonelected with traverse in the reply filed on May 8, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, note that the notation of form I is not an universal identification of compounds. It is recommended that the chemical nature of the product i.e. crystalline (+)-(S)-clopidogrel hydrogen sulphate with, PXRD pattern....etc. be incorporated so that a specific “product” can be identified by the claims.

Applicants merely assert that other U.S. patents refer to Form I clopidogrel hydrogen sulfate. This is not persuasive because an allowed application has no bearing

on the merits of the instant application. It is well recognized that the pharmaceutical art requires clear identification of the product for which description and physical characterization must be made. Chemical identity of a crystalline form should be clearly described through elemental analysis, X-ray diffraction, etc. Mere arguments by counsel does not take the place of any objective evidence. Moreover, X-ray diffraction patterns are not the sole parameter for chemical identification because the same chemical material with identical crystalline form can have drastically different powdered diffraction pattern while same X-ray diffraction pattern can be drawn to different chemicals. Note Bernstein, p. 118 vs. p.272, newly supplied to show factual evidence.

Allowable Subject Matter

Claims 57-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 56 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia L. Morris/
Primary Examiner, Art Unit 1625

plm
December 15, 2008

